

# Risk management in intensive therapy units — the method of determination of black spots

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## Abstract

**Background.** Patients hospitalised in intensive care units are more likely to suffer an adverse event than those treated in other hospital wards. The aim of this study was to assess the usefulness of identifying the events (the so-called 'black spots') that constitute a significant threat to life and health of patients and/or financing of the hospital.

**Methods.** We retrospectively analysed 30 medical records and other documents relating to the stay of patients hospitalised in the Department of Anaesthesiology and Intensive Therapy at the Regional Hospital in Swidnica in 2010. To determine the 'black spots', the authors used their own methods.

**Results.** We identified 31 adverse events (12 types of events) that occurred during the provision of healthcare in the intensive care unit. Six black spots were determined based on the model adopted in the study.

**Conclusions.** Identifying black spots can help to substantially reduce morbidity and mortality in hospitalised patients. It also allows optimisation of therapeutic entities, particularly in intensive care units.

**Key words:** method of determining black spots, risk management, adverse events

Anaesthesiology Intensive Therapy 2012, vol. 44, no 4, 200–203

Thanks to achievements of modern knowledge, science and technology as well as advances in medicine, the diseases, which were incurable or led to death several decades ago, no longer pose major medical problems; some of them do not even require hospitalisation. However, their treatment is likely to be associated with invasive diagnostic examinations or complicated operative procedures, which increase the risk of adverse events, i.e. harm caused during or resulting from the treatment, unrelated to the natural course of disease or patient's health state. In patients hospitalised in intensive care units (ICUs), the probability of adverse events is higher compared to patients treated in other hospital departments. This higher risk is attributable not only to the specificity of ICU but also to the patient's health condition [1, 2, 3, 4, 5].

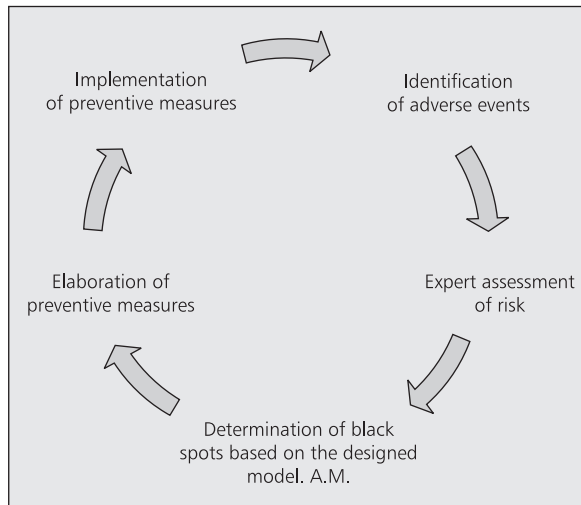
The aim of the study was to assess the usefulness of the method determining black spots in the ICU to identify the

events that pose a threat to life or health of patients and/or hospital finances (so-called black spots).

## METHODS

The retrospective analysis involved 30 medical records and other documents connected with hospitalization in the Department of Anaesthesiology and Intensive Therapy of the District Specialist Hospital in Świdnica in 2010.

The method of determination of black spots used in the study consists of a variety of techniques and partial analyses. Its objective is to identify the risk, classify hazards and suggest appropriate repair actions. This method is of an algorithm-block structure and is cyclic, i.e. once the adverse events have been identified, the risks analysed, black spots selected, repair actions suggested and implemented, the entire procedure is repeated. The detailed scheme of management is presented in Figure 1.



**Figure 1.** The cycle of actions to determine black spots

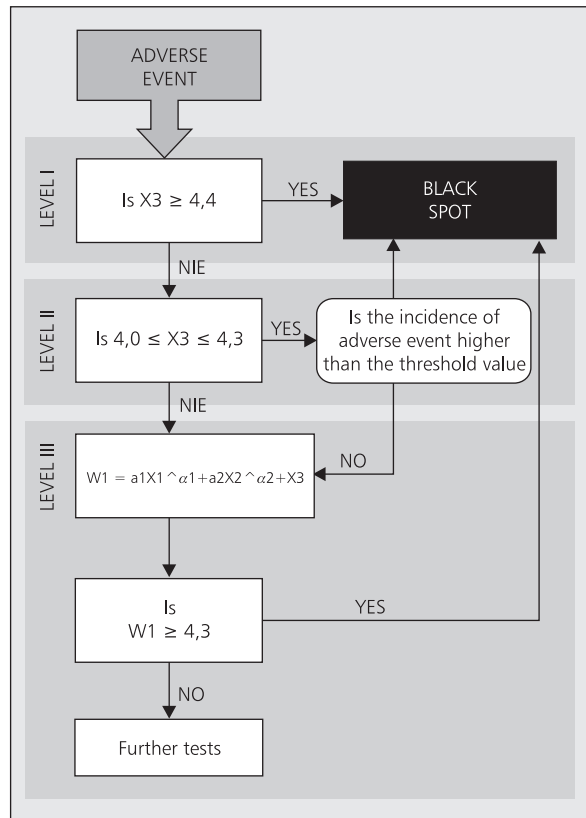
The model used to determine black spots was designed by the authors after several years of research [6, 7, 8]. The model parameters were determined using the method of identification based on minimisation of the function of loss. In the calculating construction, optimisation consisted in the survey and selection of parameters from the four-dimensional matrix, which was carried out using the computer simulation and in reduction in the number of calculations by applying the method of gradients exceeding threshold values [8]. The model used is presented in Figure 2 [9].

For the purposes of the present study, the following definition of an adverse event was assumed, „any situation, which undetected or uncorrected in time, may unambiguously lead to prolonged hospital stay, disability or death“. Adverse events were identified by physicians of a given unit and verified by the external specialist — the specialist in anaesthesiology and intensive therapy.

The identified adverse event was assessed by experts (three physicians working at a particular unit) to determine the adverse event-related patient's risk and the incidence of each identified adverse event in the unit.

The model in question assumes identification of black spots at three levels. At level I, identification regards the adverse events that constitute the highest risk for the patient (very high medical risk). At level II, identification concerns the adverse events which carry high risk for the patient, their incidence is substantial and treatment is associated with marked financial expenditure (high medical and economic risk) whereas at level III those without high medical risk but economically relevant (medium medical yet high economic risk).

Once the adverse events have been identified (i.e. black spots), the actions to eliminate them are suggested.



**Figure 2.** Model of determination of black spots

X1 — normal cost; X2 — cost of complications\*incidence; X3 — expert opinion;  $a_1 = 0.009$ ;  $a_2 = 0.0006$ ;  $\alpha_1 = 0.42675$ ;  $\alpha_2 = 1.4423$

## RESULTS

Based on analysis of medical records, 31 adverse events were identified (12 types of events), which occurred during provision of health care services in the ICU. They included: supraventricular tachycardia (n = 3), gastrointestinal haemorrhage (n = 1), haemorrhage from the tracheotomy wound requiring revision (n = 1), atrial fibrillation (n = 2), sudden cardiac arrest (n = 9), unintentional extubation (n = 2), endotracheal tube obturation (n = 1), pneumothorax (n = 1), acute respiratory distress (n = 7), upper respiratory tract infection (n = 2), *Acinetobacter baumannii* infection of the postoperative wound (n = 1), otitis media (n = 1).

The adverse events identified were assessed by experts to determine their risk for the patient and the incidence of each event in the ICU. The results are presented in Table 1.

During the next stage, black spots were identified. The results are presented in Table 2.

When the most relevant adverse events (determination of black spots) were identified, the strategy of repair actions was prepared and sent to the Manager of the District Specialist Hospital in Świdnica for implementation.

**Table 1.** Expert assessment of the risk and incidence of adverse events in intensive therapy unit

Adverse event	Risk for the patient <sup>1</sup> (1–5 scale)	Incidence of adverse events <sup>1</sup> (1–5 scale)
Supraventricular tachycardia	1.33	3
Gastrointestinal haemorrhage	5	1.67
Haemorrhage from the tracheostomy wound requiring surgical revision	3	1.33
Atrial fibrillation	2.67	5
Sudden cardiac arrest	5	2.33
Unanticipated extubation	3	1.33
Endotracheal tube obturation	3.67	2
Pneumothorax	3.33	1.33
Acute respiratory distress	4.33	1.67
Upper respiratory tract infection	1.67	2.67
<i>Acinetobacter baumannii</i> infection of the post-operative wound	2	1
Otitis media	1.67	1

<sup>1</sup>The use of the method of black spots may contribute to markedly reduced morbidity and mortality of patients, not only those treated in intensive therapy units

<sup>2</sup>The method in question enables optimisation of activities of therapeutic entities, intensive therapy units, in particular

<sup>3</sup>Determination of black spots can be used as an index of treatment quality

**Table 2.** Compilation of black spots determined at various levels of hierarchy in the intensive therapy unit

Adverse event	Black spot		
	Level I	Level II	Level III
Gastrointestinal haemorrhage	Yes	–	–
Tracheostomy wound haemorrhage requiring revision	–	–	Yes
Sudden cardiac arrest	Yes	–	–
Unanticipated extubation	–	–	Yes
Endotracheal tube obturation	–	–	Yes
Acute respiratory distress	–	Yes	–

## DISCUSSION

In the available literature, the adverse event is most commonly defined as any harm during or resulting from the treatment, unrelated to the natural course of disease or patient's health state. According to some authors, adverse events are situations resulting from medical interventions, which are responsible for patient's harm (death, life-threatening diseases, disability, prolonged hospital stay, and others) [10].

For the purposes of this study, we assumed the definition, which was not limited by harm occurrence. Thanks to this change in definition, the adverse event was any situation, which unambiguously might have led to prolonged hospital stay, disability or death but was noticed in time and appropriate management was instituted to prevent damage. Thus, the assumed adverse event definition is identical with the definition of a critical event.

The two currently used and supplementary methods of risk measurement focus on identification of problems, formulation of strategies to correct them and assessment of the effectiveness of the actions implemented ("the room-for-improvement model"), or on the monitoring system, which

is to detect problems that are periodically assessed using quality indices ("the monitoring model") [11].

The method of determination of black spots is the third option. It categorises adverse events into two groups. The first group includes adverse events identified as black spots (at level I, II and III). The second group contains adverse events not identified as black spots, i.e. less significant from the medical or economic point of view.

A relevant stage in the method of black point determination is the suggestion of solutions eliminating the adverse events identified as black spots. The effectiveness of the solutions used is verified empirically by re-identification of adverse events and subsequent determination of black spots. When the black spots identified earlier have not occurred, the solutions are considered effective.

The method designed by the authors for determination of black spots is a novel technique. However, the studies carried out to date indicate that the method can be used and enables optimisation of activities of health care institutions in many respects: medical, economic or even logistic effectiveness. Thanks to such a method, "the map of black

spots" can be prepared and, more importantly, repair actions have to be undertaken (administrative). Once the black spots have been determined, some preventive measures can be proposed — the techniques of risk management.

In the present study, from 12 identified types of adverse events, six were recognised as black spots. These included sudden cardiac arrest, acute respiratory distress, gastrointestinal haemorrhage, haemorrhage from the tracheotomy wound requiring revision, unintentional extubation, and tracheal tube obturation.

Thirty-one adverse events identified in 30 medical records are consistent with the data from other intensive therapy units published in literature. Valentin and co-workers [3] found 584 adverse events in 391 patients during the 24-hour observation of 1913 patients hospitalised in 205 ICUs.

Surprisingly, amongst 12 identified types of adverse events there were no cases attributable to improper supply of drugs, disconnection of vascular lines, drains, and others, which are the adverse events most commonly identified in literature reports [3]. This is most likely associated with the imperfectness of the method of identification of adverse events (data from medical records). Moreover, the fact that some adverse events remain unrevealed is of importance — events unrecorded in medical records due to possible legal, civil or disciplinary consequences. According to the authors, legal obligation to report each adverse event in the hospital (confidential register) should enable to assess the extent of the problem and to increase the safety of patients.

The black spots determined in the study are generally considered the events related to increased morbidity and mortality. For instance, in the study concerning unintentional extubation among 197 patients treated in intensive therapy units, 24 patients experienced this event. Re-intubation was necessary in 20 cases (74%). The main indication for re-intubation was acute respiratory distress (90%). In one case, the patient died [1].

The authors believe that the repair activities suggested will significantly contribute to decreased numbers of black spots, thus reducing morbidity and mortality in the intensive therapy units.

Identification of adverse events and their classification enable us to understand how many factors and elements can affect their occurrence. The cause of error may be associated with lack of proper qualifications or cooperation of the specialists involved in the diagnostic-therapeutic process (e.g. physicians, nurses, technicians, laboratory technicians) or the head of the unit as well as with the medical devices the unit is equipped with.

The comprehensive knowledge about adverse events (black spots) is essential for identification of the source of possible dangers and selection of those that cause the high-

est harm and are of importance for proper functioning of the entire therapeutic institution, including the patient's safety.

However, the collection of all the necessary information is extremely difficult and tedious, requiring not only adequate experience but also knowledge about the organizational structure of the therapeutic institution and its specificity.

## CONCLUSIONS

1. The use of the method of black spots may contribute to markedly reduced morbidity and mortality of patients, not only those treated in intensive therapy units.
2. The method in question enables optimisation of activities of therapeutic entities, intensive therapy units, in particular.
3. Determination of black spots can be used as an index of treatment quality.

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Received: 24.05.2012

Accepted: 3.07.2012